111TH CONGRESS
1ST SESSION

S. 754

To provide for increased Federal oversight of methadone treatment.

IN THE SENATE OF THE UNITED STATES

MARCH 31, 2009

Mr. ROCKEFELLER (for himself, Mr. CORKER, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for increased Federal oversight of methadone treatment.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Methadone Treatment and Protection Act of 2009''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Methadone is an extensively tested, federally approved, and widely accepted method of effective treatment.

(2) For more than 30 years, this synthetic prescription drug has been used for pain management and treatment for addiction to heroin, morphine, and other opioid drugs.

(3) The efficacy and lower cost of methadone has resulted in its being prescribed for pain management.

(4) Prescriptions for methadone have increased by nearly 700 percent from 1998 through 2006.

(5) As with any controlled substance, there is a risk of abuse of methadone.

(6) According to the Centers for Disease Control and Prevention, in 2005, there were 4,462 methadone-related deaths, representing an increase of 468 percent since 1999. By contrast, all poisoning deaths by all drugs increased by 66 percent over the same period.

(7) The age-specific rates of methadone death are higher for persons age 35 to 44 and 45 to 54 than for other age groups. However, the rate of methadone deaths in younger individuals (age 15 to 24) increased 11-fold from 1999 through 2005.

(8) Deaths from methadone may actually be underreported. There is no comprehensive database of drug-related deaths in the United States.

(9) The lack of standardized reporting by Medical Examiners precludes a uniform definition of ''cause of death'' on death certificates.

(10) While the Controlled Substances Act (21 U.S.C. 801 et seq.) requires additional registration for practitioners who dispense schedule II narcotics, including methadone, for both pain management and addiction treatment, there is no specific education requirements for practitioners to prescribe methadone for pain management.

(11) Current Federal oversight of methadone is inadequate to address the growing number of methadone-related deaths.

(12) Federal legislation is needed to increase Federal oversight over methadone treatment, both as part of opioid treatment programs and as part of the treatment of pain, without reducing patient access.

SEC. 3. CONSUMER EDUCATION CAMPAIGN.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

''SEC. 506C. CONSUMER EDUCATION CAMPAIGN.

''(a) IN GENERAL.—The Administrator shall award grants to States and nonprofit community organizations

for the purpose of educating consumers about the dangers of opioid abuse, including methadone abuse, through educational materials that are culturally sensitive.

''(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a State or nonprofit community organization; and

''(2) submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

''(c) PRIORITY.—In awarding grants under this section, the Administrator shall give priority to applicants that are States or communities with a high-incidence of methadone abuse and methadone-related deaths.

''(d) EVALUATIONS.—The Administrator shall develop a process to evaluate the effectiveness of activities carried out by grantees under this section at reducing methadone abuse.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2010 through 2014.''.

SEC. 4. PRACTITIONER EDUCATION.

(a) EDUCATION REQUIREMENTS.—

(1) REGISTRATION CONSIDERATION.—Section 303(f) of the Controlled Substances Act (21 U.S.C.

823(f)) is amended by inserting after paragraph (5) the following:

''(6) The applicant's compliance with the training requirements described in subsection (g)(3) during any previous period in which the applicant has been subject to such training requirements.''.

(2) TRAINING REQUIREMENTS.—Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended by adding at the end the following:

''(3)(A) To be registered to prescribe or otherwise dispense methadone or other opioids, a practitioner described in paragraph (1) shall comply with the 16-hour training requirement of subparagraph (B) at least once during each 3-year period.

''(B) The training requirement of this subparagraph is that the practitioner has completed not less than 16 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) with respect to—

''(i) the treatment and management of opiate-dependent patients; and

''(ii) pain management treatment guidelines,

that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteo-

pathic Association, the American Psychiatric Association, the American Academy of Pain Management, the American Pain Society, the American Academy of Pain Medicine, the American Board of Pain Medicine, or any other organization that the Secretary determines is appropriate for purposes of this subparagraph.''.

(b) REQUIREMENTS FOR PARTICIPATION IN OPIOID TREATMENT PROGRAMS.—Effective July 1, 2009, a physician practicing in an opioid treatment program shall comply with the requirements of section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) with respect to required minimum training at least once during each 3-year period.

(c) DEFINITION.—In this section, the term ''opioid treatment program'' has the meaning given such term in section 8.2 of title 42, Code of Federal Regulations (or any successor regulation).

(d) FUNDING.—The Drug Enforcement Administration shall fund the enforcement of the requirements specified in section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) through the use of a portion of the licensing fees paid by controlled substance prescribers under the Controlled Substances Act (21 U.S.C. 801 et seq.).

SEC. 5. MORATORIUM ON METHADONE HYDROCHLORIDE TABLETS.

(a) IN GENERAL.—Notwithstanding any other provision of law, during the period beginning on the date of enactment of this Act and ending on the date described in subsection (b), no individual or entity may prescribe or otherwise dispense a 40-mg diskette of methadone unless such prescription or dispensation is consistent with the methadone policy implemented by the Drug Enforcement Administration on the date of enactment of this Act, except that such prohibition shall extend to opioid treatment programs and hospitals unless such programs or hospitals provide for direct patient supervision with respect to such methadone. During such period, no take home dosages of 40-mg diskettes of methadone shall be permitted.

(b) ENDING DATE OF MORATORIUM.—The moratorium under subsection (a) shall cease to have force and effect—

(1) on the date that the Controlled Substances Clinical Standards Commission publishes in the Federal Register dosing standards for all forms of methadone, in accordance with section 506D(b)(1)(A) of the Public Health Service Act (as added by section 7); and

(2) if, as part of such dosing standards, such Commission finds that 40-mg diskettes of methadone are safe and clinically appropriate.

SEC. 6. OPERATION OF OPIOID TREATMENT PROGRAMS.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(i)(1) An opioid treatment program that is registered under this section, and that closes for business on any weekday or weekend day, including a Federal or State holiday, shall comply with the requirements of this subsection.

''(2) The program shall make acceptable arrangements for each patient who is restricted, by Federal regulation or guideline or by the determination of the program medical director, from having a take home dose of a controlled substance related to the treatment involved, to receive a dose of that substance under appropriate supervision during the closure.

''(3) The Administrator of the Substance Abuse and Mental Health Services Administration shall issue a notice that references regulations on acceptable arrangements under this subsection, or shall promulgate regulations on such acceptable arrangements.''.

SEC. 7. ESTABLISHMENT OF THE CONTROLLED SUBSTANCES CLINICAL STANDARDS COMMISSION.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by section 3, is further amended by adding at the end the following:

"SEC. 506D. ESTABLISHMENT OF THE CONTROLLED SUBSTANCES CLINICAL STANDARDS COMMISSION.

''(a) IN GENERAL.—The Secretary shall establish a Controlled Substances Clinical Standards Commission (referred to in this section as the 'Commission'), to be composed of representatives from the Administration, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Pain Management Consortia of the National Institutes of Health, to develop—

''(1) appropriate and safe dosing standards for all forms of methadone, including recommendations for maximum daily doses of all forms as provided for in subsection (b)(1);

''(2) benchmark standards for the reduction of methadone abuse, as provided for in subsection (b)(2);

''(3) appropriate conversion factors for use by health care providers in transitioning patients from one opioid to another;

''(4) specific guidelines for initiating pain management with methadone that prescribing physicians shall comply with in order to meet certification requirements set forth in part C of the Controlled Substances Act (21 U.S.C. 821 et seq.); and

''(5) patient and practitioner education standards for both methadone maintenance therapy and pain management that apply to safe and effective use and include detoxification.

''(b) STANDARDS.—

''(1) PUBLICATION OF DOSING STANDARDS.—

''(A) IN GENERAL.—Not later than 2 years after the date of enactment of the Methadone Treatment and Protection Act of 2009, the Commission established under subsection (a) shall publish in the Federal Register—

''(i) safe and clinically appropriate dosing standards for all forms of methadone used for both pain management and opioid treatment programs, including recommendations for maximum daily doses of all forms, including recommendations for the induction process for patients who are newly prescribed methadone;

"(ii) requirements for individual patient care plans, including initial and follow-up patient physical examination standards, and recommendations for screening patients for chronic or acute medical conditions that may cause an immediate and adverse reaction to methadone;

"(iii) appropriate conversion factors for use by health care providers in transitioning patients from one opioid to another; and

"(iv) specific guidelines for initiating pain management with methadone, that prescribing physicians shall comply with in order to meet Drug Enforcement Administration certification and re-certification requirements.

"(B) UPDATING OF STANDARDS.—Not later than 3 years after the publication of standards under subparagraph (A), and at least every 3 years thereafter, the Commission shall update such standards.

"(2) PUBLICATION OF BENCHMARK STANDARDS.—

''(A) IN GENERAL.—Not later than 3 years after the date of enactment of the Methadone Treatment and Protection Act of 2009, the Commission established under subsection (a) shall publish in the Federal Register—

''(i) the initial benchmark standards for the reduction of methadone abuse to be used—

''(I) by opioid treatment programs in providing methadone therapy; and

''(II) by entities in the initial accreditation or certification, and the re-accreditation and re-certification, of such opioid treatment programs;

''(ii) a model policy for dispensing methadone to be used by pharmacists that dispense methadone, which should include education and training standards for such pharmacists;

''(iii) the continuing education standards that all prescribers shall comply with in order to meet Drug Enforcement Administration certification and re-certification requirements, as set forth in section

303(g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(3)), which should include a minimum of 16 training hours at least every 3 years that include the integration of both addiction and pain management curricula; and

''(iv) patient education standards for both opioid treatment programs and pain management, including recommendations for patient counseling prior to and during opioid addiction treatment or treatment for pain.

''(B) UPDATING OF STANDARDS.—Not later than 1 year after the publication of standards under subparagraph (A), and at least annually thereafter, the Commission shall update the standards published under clauses (iii) and (iv) of such subparagraph.

''(3) CONSULTATION.—In developing and publishing the standards under this section, the Commission shall consult with relevant professional organizations with expertise in the area of addiction, relevant professional organizations with expertise in the area of pain management, physician groups, pharmacy groups (including the National Association of

Boards of Pharmacy), and any other organization that the Secretary determines is appropriate for purposes of this section.

''(c) WEBSITE.—Not later than 180 days after the date of enactment of the Methadone Treatment and Protection Act of 2009, the Commission shall establish and operate a Commission website.

''(d) METHADONE TOOLKIT.—Not later than 180 days after the date of enactment of the Methadone Treatment and Protection Act of 2009, the Commission shall establish, and distribute to practitioners that are registered to prescribe or otherwise dispense methadone, a methadone toolkit. The Commission shall make the components of the toolkit that are available in electronic form available on the Commission website.

''(e) PRACTITIONER EDUCATION PROGRAM.—The Commission shall develop a practitioner education program that shall be used for the practitioner education described in section 303(g)(3) of the Controlled Substances Act, and shall make such program available to providers of such practitioner education.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.''.

SEC. 8. PRESCRIPTION MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (d)(1), by inserting ''(including prescribers of methadone)'' after ''dispensers'';

(2) in subsection (e), by adding at the end the following:

''(5) Subject to the requirements of section 543, the State shall, at the request of a Federal, State, or local officer whose duties include enforcing laws relating to drugs, provide to such officer information from the database relating to an individual who is the subject of an active drug-related investigation conducted by the officer's employing government entity.''; and

(3) by striking subsection (n) and inserting the following:

''(n) APPROPRIATIONS.—There is authorized to be appropriated, and there is appropriated, to carry out this section $25,000,000 for each of fiscal years 2010 through 2014.''.

SEC. 9. MORTALITY REPORTING.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by section 7, is further amended by adding at the end the following:

"SEC. 506E. MORTALITY REPORTING.

"(a) MODEL OPIOID TREATMENT PROGRAM MORTALITY REPORT.—

"(1) IN GENERAL.—Not later than October 1, 2009, the Secretary, acting through the Administrator, shall require that a Model Opioid Treatment Program Mortality Report be completed and submitted to the Administrator for each individual who dies while receiving treatment in an opioid treatment program.

"(2) REQUIREMENT OF STATES THAT RECEIVE FUNDING FOR THE CONTROLLED SUBSTANCE MONITORING PROGRAM.—As a condition for receiving funds under section 399O, each State shall require that any individual who signs a death certificate where an opioid drug is detected in the body of the deceased, or where such drug is otherwise associated with the death, report such death to the Administrator by submitting a Model Opioid Treatment Program Mortality Report described in paragraph (3). Such report shall be submitted to the Administrator on or before the later of—

"(A) 90 days after the date of signing the death certificate; or

"(B) as soon as practicable after the date on which the necessary postmortem and toxi-

cology reports become available to such individual, as required by the Secretary.

''(3) DEVELOPMENT.—The Administrator, in consultation with State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Administrator determines appropriate, shall develop a Model Opioid Treatment Program Mortality Report to be used under paragraphs (1) and (2).

''(b) NATIONAL OPIOID DEATH REGISTRY.—

''(1) IN GENERAL.—Not later than January 1, 2010, the Administrator shall establish and implement, through the National Center for Health Statistics, a National Opioid Death Registry (referred to in this subsection as the 'Registry') to track all aPD-related deaths and information related to such deaths.

''(2) CONSULTATION.—In establishing the uniform reporting criteria for the Registry, the Director of the Centers for Disease Control and Prevention shall consult with the Administrator, State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Director determines is appropriate for purposes of this subsection.

''(3) REQUIREMENTS.—The registry shall be designed as a uniform reporting system for aPD-related deaths and shall require the reporting of information with respect to each such death, including—

''(A) the particular drug formulation used at the time of death;

''(B) the dosage level;

''(C) a description of the circumstances surrounding the death in relation to the recommended dosage involved;

''(D) a disclosure of whether the medication involved can be traced back to a physician's prescription;

''(E) a disclosure of whether the individual was in an opioid treatment program at the time of death;

''(F) the age and sex of the individual; and

''(G) other non-personal information such as that included in filed National Association of Medical Examiners Pediatric Toxicology Registry (paddies) case reports as required under the privacy standard for the de-identification of health information pursuant to the regulations contained in part 164 of title 45, Code of Federal Regulations.

''(4) AUTHORIZATION.—There is authorized to be appropriated $5,000,000 to carry out this subsection.

''(c) REPORT ON REGISTRY INFORMATION.—Not later than the January 1 of the first fiscal year beginning 2 years after the date of enactment of the Methadone Treatment and Protection Act of 2009, and each January 1 thereafter, the Director of the Centers for Disease Control and Prevention shall submit to the Secretary a report, based on information contained in the Registry described in subsection (b), concerning the number of methadone-related deaths in the United States for the year for which the report is submitted.''.

SEC. 10. ADDITIONAL REPORTING.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by section 9, is further amended by adding at the end the following:

''SEC. 506F. ADDITIONAL REPORTING.

''(a) REPORT ON METHADONE USAGE.—

''(1) IN GENERAL.—Not later than January 1 of the first fiscal year beginning 2 years after the date of enactment of the Methadone Treatment and Protection Act of 2009, and each January 1 thereafter, the Administrator shall submit to the Secretary a report containing detailed statistics on

methadone usage for opioid treatment and pain management. Such statistics shall include—

"(A) information on the distribution of prescribed doses of methadone at federally qualified health centers, opioid treatment clinics, other health-related clinics, physician offices, pharmacies, and hospitals; and

"(B) information relating to adverse health events resulting from such methadone usage.

"(2) AVAILABILITY OF INFORMATION.—The Secretary shall make the reports submitted under paragraph (1) available to the general public, including through the use of the Internet website of the Department of Health and Human Services.

"(b) ANNUAL REPORT ON EFFECTIVENESS.—Not later than September 30, 2010, and annually thereafter until September 30, 2014, the Secretary shall submit to the appropriate committees of Congress, a report concerning the effectiveness of the methadone maintenance therapy program. Such report shall evaluate the success of efforts to reduce opioid addiction and methadone-related deaths, including the impact of health care provider and patient education.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section

such sums as may be necessary for each of fiscal years 2010 through 2014.''.

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